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FOLEY AND LARDNER LLP
SUITE 500
3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER

BOWERS, NATHAN ANDREW

ART UNIT	PAPER NUMBER
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1744

DATE MAILED: 10/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/727,037

Applicant(s)

BROWN ET AL.

Examiner

Nathan A. Bowers

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14, 26-30 and 33-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 7 and 26-30 is/are allowed.
- 6) ☒ Claim(s) 1-6, 8-14, 33-38 and 40-45 is/are rejected.
- 7) ☒ Claim(s) 39 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

- 1) Claims 1, 2, 5, 6, 9, 33, 34, 37, 38 and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Schramm (US 5935864).

With respect to claims 1 and 33, Schramm discloses an apparatus for preparing samples for analysis comprising a handle having a swab (Figure 7:39) attached at the end of the handle. The swab includes a chamber within which a stabilized reagent is placed. A sample tube (Figure 7:37) extends from an end of the chamber. The apparatus further includes a wand assembly (Figure 7:43) that comprises a buffer container at one end of the assembly, and a stand at another end of the assembly. Figures 7-9 indicate that the wand assembly is generally in the shape of a cylinder shaft, and that both ends of the assembly are planar and therefore capable of being used as a stand. Column 4, line 43 to column 5, line 29 indicates that the handle is configured to be attached to the wand assembly in order to analyze a sample that has been collected on the swab. Schramm teaches that the apparatus is designed for testing biological samples such as blood, however does not indicate exactly what types of buffers and reagents are used. Schramm's invention is inherently capable for use in PCR analysis provided that the appropriate buffers and reagents are loaded within the disclosed apparatus.

With respect to claims 2 and 34, Schramm discloses the apparatus in claims 1 and 33, wherein the buffer container includes a film (Figure 7:44) covering one end of the container. This is disclosed in column 4, lines 55-59.

With respect to claims 5 and 37, Schramm discloses the apparatus in claims 1 and 33, wherein the handle removably attaches to the wand assembly by inserting the swab into the shaft of the wand assembly. Column 4, lines 55-59 teach that the swab is pushed through the film covering the container, and that the swab is inserted into the shaft of the wand assembly in this manner.

With respect to claims 6 and 38, Schramm discloses the apparatus in claims 1 and 33, wherein a cover of the handle is configured to detach from the swab when the swab is attached to the wand assembly. Figures 7-9 indicate that the sample tube (Figure 7:37) comprises a cover, and can be removed from the swab assembly (Figure 7:39) when the swab is mated to the wand assembly.

With respect to claims 9 and 41, Schramm discloses the apparatus in claims 1 and 33, wherein the handle and wand assembly are configured to be portable. This is apparent from Figure 3, which shows the apparatus in proportion to a person's hand. Furthermore, all of the necessary reagents and buffers are entirely contained within the apparatus, thus inherently contributing to its portability.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

2) Claims 1, 2, 4-6, 9, 33, 34, 36-38 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schramm (US 5935864) in view of Davis (US 20050059165).

With respect to claims 1, 2, 5, 6, 9, 33, 34, 37, 38 and 41, Schramm discloses the apparatus as previously described above. However, if the capillary tube disclosed by Schramm cannot be considered a swab, then Schramm fails to anticipate claims 1 and 33.

Davis discloses a sample collection device. In paragraphs [0044]-[0046], Davis indicates that swabs (Figure 1:48) and capillary tubes (Figure 1:46) are interchangeable structures that are each fully capable of acquiring biological analytes.

Schramm and Davis are analogous art because they are from the same field of endeavor regarding biological sample collecting apparatuses and methods.

At the time of the invention, it would have been obvious to exchange the capillary tube disclosed by Schramm with a more conventional swab device. Davis indicates that these structures are functionally equivalent devices and that they are interchangeable in use. If it was determined that a swab would more effectively remove analytes from a desired surface, it would have been apparent to equip Schramm's device with a swab rather than, or in combination with, the disclosed capillary tube. It is believed that Schramm's device is fully capable of accommodating the addition of a conventional swab.

With respect to claims 4 and 36, Schramm and Davis disclose the apparatus set forth in claims 1 and 33 as set forth in the 35 U.S.C. 103 rejection above. In addition, Schramm discloses in column 4, lines 49-51 that the chamber includes a vent (Figure 7:41). Schramm, however, does not indicate that the chamber includes a plurality of vents. Regardless, it would have been obvious to include multiple vents if it is known that the single vent is unable to effectively disperse air that is displaced by the buffer solution. In this way, one would avoid the build up of excess pressure. In general, the mere duplication of parts has no patentable significance unless a new and unexpected result is produced. See *In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960).

3) Claims 3 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schramm (US 5935864) and Davis (US 20050059165) as applied to claims 1 and 33, and further in view of Wickstead (US 6634243).

Schramm and Davis disclose the apparatus set forth in claims 1 and 33 as set forth in the 35 U.S.C. 103 rejection above, however do not expressly disclose that the wand assembly further comprises a spike to rupture the buffer container.

Wickstead discloses an apparatus for preparing samples that comprises a buffer chamber (Figure 1:10) and a sample container (Figure 1:20). The buffer chamber and sample container are able to fit inside a handle (Figure 1:50) comprising a reagent test strip (Figure 1:40). This is disclosed in column 4, line 39 to column 5, line 40 and column 7, lines 28-30. The sample container includes a spike (Figure 7:24) that is capable of rupturing a membrane (Figure 1:18) on the buffer chamber in such a way to allow the buffer to exit the container.

Schramm, Davis and Wickstead are analogous art because they are from the same field of endeavor regarding sample preparation apparatuses.

At the time of the invention, it would have been obvious to equip the wand assembly proposed by Schramm with a spike capable of rupturing the frangible membrane on the buffer container when the handle is connected with the wand assembly. This would have been beneficial because one would no longer need to use the swab itself to break the frangible membrane. Since directly contacting the swab to the membrane might lead to sample contamination or damage to the swab, it would have been advantageous to provide the wand

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assembly with a separate spike that is activated when the handle is mated with the wand assembly.

4) Claims 8, 10, 40 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schramm (US 5935864) and Davis (US 20050059165) as applied to claims 1 and 33, and further in view of DiCesare (US 20020001539).

With respect to claims 8 and 40, Schramm and Davis disclose the apparatus set forth in claims 1 and 33 as set forth in the 35 U.S.C. 103 rejection above, however do not expressly indicate that the stand is configured to attach to a slot in a hand-held detector for biological materials.

DiCesare discloses an apparatus for preparing samples comprising a handle (Figure 4:17) having a chamber (Figure 4:23). A swab (Figure 5:27) is attached to an end of the handle, and the chamber includes a reagent. This is disclosed in paragraph [0065]. A wand assembly (Figure 4:55) is provided, and includes a container (Figure 5:36) at an end of a shaft and a stand at another end of the shaft. Paragraphs [0057] and [0075] indicate that the wand assembly is inserted into the sample port of a portable, hand-held device.

Schramm, Davis and DiCesare are analogous art because they are from the same field of endeavor regarding biological sample collecting device.

At the time of the invention, it would have been obvious to ensure that the device proposed by Schramm is attachable to a slot in a hand-held detector. This would have been advantageous because it would have allowed the collected sample to be immediately analyzed in the field. By fitting the stand directly in a detector, one would have been able to avoid

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transferring the sample into a separate analysis tube, thereby avoiding potential contamination and fluid loss.

With respect to claims 10 and 42, Schramm and Davis disclose the apparatus set forth in claims 1 and 33 as set forth in the 35 U.S.C. 103 rejection above. Schramm also discloses a corresponding method in which the apparatus is used to analyze a biological sample. The swab is wiped over a test surface, and is brought into contact with the wand assembly. A buffer container in the wand assembly is ruptured in order to enable buffer to flow over the swab and into a chamber for mixing with a reagent. Schramm, however, does not expressly indicate that the swab comprises an additional absorbent material attached to the end of the swab.

DiCesare discloses the apparatus as previously described. In paragraphs [0013]-[0024], DiCesare indicates that the use of absorbent swabs to collect biochemical analytes is well known in the art.

Schramm, Davis and DiCesare are analogous art because they are from the same field of endeavor regarding sample preparation devices.

At the time of the invention, it would have been obvious to supply Schramm's apparatus with an absorbent material at the end of the disclosed swab. Absorbent swabs are known in the art to effectively collect a variety of biological materials. The use of absorbent materials in Schramm's device would be beneficial because absorbent materials would be able to effectively move the sample to the reagent chamber through the addition of a buffer and a subsequent wicking action. This is described by DiCesare in paragraph [0024]. DiCesare further indicates

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in paragraph [0020] that absorbent materials are favored in the art because a number of solutions and reagents can be applied to them to facilitate the initial collection of samples.

5) Claims 11 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schramm (US 5935864), Davis (US 20050059165) and DiCesare (US 20020001539) as applied to claims 10 and 42, and further in view of Mennen (US 4562043).

Schramm, Davis and DiCesare disclose the apparatus set forth in claims 10 and 42 as set forth in the 35 U.S.C. 103 rejection above, however do not expressly disclose that the absorbent material is held in place by a retaining ring.

Mennen discloses an apparatus for preparing a sample for analysis. The apparatus comprises a swab (Figure 1:22) made from an absorbent material, and a chamber (Figure 1:24) that contains a reagent. The absorbent swab is attached to the apparatus through a heat sealing method that produces an indented area (Figure 7:20) that acts as a retaining ring. This is disclosed in column 7, line 65 to column 8, line 21. The absorbent swab is used for collecting a variety of different biological samples.

Schramm, Davis, DiCesare and Mennen are analogous art because they are from the same field of endeavor regarding sample preparation devices.

At the time of the invention, it would have been beneficial to attach the absorbent material to the end of the swab disclosed by Schramm, Davis and DiCesare using a retaining ring. The use of a retaining ring would ensure that the swab is not dislodged from the apparatus during sample collection, and therefore would make the apparatus less susceptible to damage.

6) Claims 12, 13, 44 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schramm (US 5935864) in view of Davis (US 20050059165) and DiCesare (US 20020001539) as applied to claims 10 and 42, and further in view of Berke (US 5084045).

Schramm, Davis and DiCesare disclose the apparatus and method set forth in claims 10 and 42 as set forth in the 35 U.S.C. 103 rejection above, however do not expressly disclose positioning a mesh cover underneath and above the absorbent material.

Berke discloses an apparatus and method for preparing samples for analysis. Biological specimens are collected upon a swab (Figure 3:58) and transferred to a reaction area (Figure 1:42, 44). This is disclosed in column 9, line 39 to column 10, line 42. Column 10, lines 43-57 indicate that a filter (Figure 1:52) is positioned between the swab and the reaction area so that biological analytes collected by the swab are allowed to pass through to the reaction area, but solid swab particles are not.

Schramm, Davis, DiCesare and Berke are analogous art because they are from the same field of endeavor regarding sample preparation devices.

At the time of the invention, it would have been obvious to position a filter/mesh material one both sides of the absorptive swab disclosed by Schramm, Davis and DiCesare. This would have been beneficial because the mesh would have securely supported the absorptive swab material on the handle, and would have ensured that it would not be broken or damaged during sample collection. The mesh would have also been advantageous because it would not have interfered with the transfer of the buffer from the wand assembly, through the absorptive material, and into the reagent chamber.

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7) Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schramm (US 5935864) in view of Davis (US 20050059165) and DiCesare (US 20020001539) as applied to claim 10, and further in view of Sangha (US 20030113906).

Schramm and DiCesare disclose the apparatus set forth in claim 10 as set forth in the 35 U.S.C. 103 rejection above, however do not expressly disclose the use of paper as the absorbent material.

Sangha discloses an apparatus for collecting biological samples from a surface that comprises swap composed of an absorbent material (Figure 1:20). In paragraph [0036], Sangha teaches that IsoCode paper is suitable for use as this type of collection substrate.

Schramm, Davis, DiCesare and Sangha are analogous art because they are from the same field of endeavor regarding device for the collection of biological samples.

At the time of the invention, it would have been obvious to utilize paper as the absorbent material within the apparatus disclosed by Schramm, Davis and DiCesare. In paragraph [0036], Sangha teaches that paper can be manufactured to have a sticky or adhesive surface, which aids in the collection of biological samples. In paragraph [0042], Sangha states that paper is also beneficial because it is versatile in its operation, since paper can be used in both dry and wetted states to collect samples.

Allowable Subject Matter

Claim 39 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 7 and 26-30 are allowed.

Claims 7, 26-30 and 39 include limitations regarding a wand assembly with an extendable grip. Claim 26 further involves “whipping” the apparatus after the grip on the wand is extended. The prior art does not disclose an apparatus for preparing samples that is designed to be “whipped” and includes all of the limitations set forth in claims 1 and 25. Since the purpose of the extendable grip is to facilitate “whipping,” it is natural that this limitation is also not found in the prior art. The closest art is represented by Zhou (US 20040184966), which cannot be considered prior art due to its date. Zhou discloses a biological specimen collection device with a telescoping grip. The telescoping grip is connected to a sample collection swab and allows the user to access remote samples due to the extension of the grip. Even if Zhou was prior art, it could not be combined with Schramm or DiCesare because there is no motivation to add an extendable grip to the wand assembly. Zhou would only give motivation to add an extendable grip to Schramm and DiCesare’s handle assemblies since the handle assemblies are connected to the swabs and are used for collecting samples. References similar to Zhou that are prior art regarding extendable handle assemblies could not be used to reject claims 7 and 26 for the same reason.

Double Patenting

Applicant has asked that double patenting rejections be held in abeyance until patentability of the claims in the application is resolved. However, all previously asserted double patenting rejections still are maintained to be proper and pertinent at the present time.

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The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 5, 9, 10, 12, 25, 27, 29 and 32 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 4, 12-17, 20, 26 and 34 of Application No. 10/852684. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant application is generic to the Application No. 10/852684. Application No. 10/852684 includes limitations regarding a buffer container, a swab and a stabilized reagent chamber. The buffer container housing disclosed by Application No. 10/852684 is considered to be equivalent to the wand assembly disclosed in the instant application. Application No. 10/852684 states that the swab/reaction tube housing is configured to be attached to the buffer container housing. The instant application is deemed to be generic to Application No. 10/852684 because Application No. 10/852684 includes additional limitations regarding a plunger housing.

Response to Arguments

In response to Applicant's amendments, all claim objections and rejections made under 35 U.S.C. 112 have been withdrawn.

Applicant's arguments, see pages 9 and 10, filed 7 August 2006, with respect to the rejections made under 35 U.S.C. 102 under DiCesare have been fully considered and are persuasive. These rejections of claims 1, 2, 5 and 8-10 have been withdrawn.

Applicant's arguments filed 7 August 2006 in regard to the 35 U.S.C. 102 rejections involving Schramm have been fully considered but they are not persuasive.

Applicant's principle arguments are

(a) Schramm does not disclose a swab that includes a stabilized reagent in a chamber.

Instead, Schramm discloses a capillary having an open capillary end.

In response to Applicant's arguments, please consider the following comments.

The capillary described by Schramm is considered to be a "swab." The term swab is defined in Applicant's specification as merely an absorbent material. Since the capillary disclosed by Schramm draws liquids into the reaction chamber through absorption, it is believed that the capillary must be considered a swab. In the absence of additional, positively stated limitations regarding the nature of the claimed swab, Schramm's capillary must be considered a swab, especially when taken in light of Applicant's specification.

Please also consider the additional rejection made in view of the combination of Schramm and Davis.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

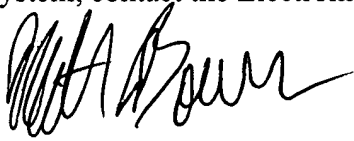
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan A. Bowers whose telephone number is (571) 272-8613. The examiner can normally be reached on Monday-Friday 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on (571) 272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



NAB



GLADYS JP CORCORAN
SUPERVISORY PATENT EXAMINER